

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Tom C. Xu

Applicant's Ref: XUTOM01

Application No.: 10/038,263

Examiner: ALEXANDER, LYLE

Filed: 10/24/2001

Group Art Unit: 1797

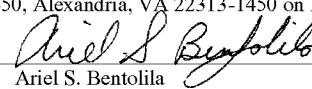
Title: Diagnostic Test Optical Fiber Tips

Date: February 26, 2009

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being electronically transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 26, 2009.

Signed:



Ariel S. Bentolila

AMENDMENT C

Commissioner for Patents
Mail Stop RCE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant submits this Amendment After Final to address the Office Action having a mailing date of 10/28/2008, the three-month period for response, which extends through 01/28/2009. The favorable reconsideration of the above-identified application in view of the following amendments and comments is respectfully requested, which response is submitted concurrently with the Request for Continued Examination (RCE) filed herewith.

THE FOLLOWING IS A LISTING OF THE CURRENTLY PENDING CLAIMS:

1-104 (Canceled)

105.(Currently amended) A test tip device for a photometrical detector used for measuring a quantity of an analyte in a sample volume, the device comprising:

an optical fiber comprising at least one fiber, a first and second end and a first diameter along an entire length of said optical fiber, said first end receiving a light from the photometrical detector for transmission through said optical fiber to said second end;

a reagent pad comprising a flat membrane material impregnated with a dried reagent solution that comprises oxidase/peroxidase enzymes and optical properties that change with the quantity of the analyte, said flat membrane material formed in a circular shape with a second diameter matching said first diameter for substantially covering said second end while minimizing an area of said reagent pad, said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing; and

means for bonding said second flat surface to said second end where said light impinges on said second flat surface and a reflected light, from said second flat surface, indicating changes in said optical properties is effectively returned through said optical fiber to the photometrical detector where the quantity of the analyte in the minimized size of the sample volume can be measured in vitro.

106.(Previously presented) The device as recited in claim 105, wherein said first end is removably inserted into a detection slot of the photometrical detector and the

test tip device is disposable.

107.(Previously presented) The device as recited in claim 105, wherein said first and second ends are polished for efficiency of light conduction.

108.(Previously presented) The device as recited in claim 105, wherein said change in optical properties is a color change.

109.(Previously presented) The device as recited in claim 105, wherein said flat membrane material further comprises a uniformly porous hydrophilic membrane.

110.(Canceled)

111.(Currently amended) The device as recited in claim 105, wherein said reagent solution reacts to blood glucose and the quantity of the analyte blood glucose in the minimized size of the sample volume is measured by the photometrical detector in an in vitro blood glucose self-monitoring system.

112.(Currently amended) A test tip device for a photometrical detector used for measuring a quantity of an analyte in a sample volume, the device comprising:

a micro tube comprising a first open end, a second closed end and a first diameter along an entire length of said micro tube, said second closed end comprising an interior surface and an exterior surface wherein said first open end and said interior surface of said second closed end defines a cavity of said micro tube and said first open end and said exterior surface of said second closed end defines said entire length of said micro tube, said first open end receiving an optical probe from the photometrical detector where the optical probe passes through said cavity to said interior surface of said second end;

a reagent pad comprising a flat membrane material impregnated with a dried reagent solution that comprises oxidase/peroxidase enzymes and optical properties that change with the quantity of the analyte, said flat membrane material formed in a circular shape with a second diameter matching said first diameter for substantially covering said second closed end while minimizing an area of said reagent pad, said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing; and

means for bonding said second flat surface to said exterior surface of said second end where light from the optical probe impinges on said second flat surface and a reflected light, from said second flat surface, indicating changes in said optical properties is effectively returned through the optical probe to the photometrical detector where the quantity of the analyte in the minimized size of the sample volume can be measured in vitro.

113.(Original) The device as recited in claim 112, wherein the optical probe is removably inserted into said first open end and the test tip device is disposable.

114.(Original) The device as recited in claim 112, wherein said change in optical properties is a color change.

115.(Original) The device as recited in claim 112, wherein said flat membrane material further comprises a uniformly porous hydrophilic membrane.

116.(Canceled)

117.(Currently amended) The device as recited in claim 112, wherein said reagent solution reacts to blood glucose and the quantity of the analyte blood glucose in

the minimized size of the sample volume is measured by the photometrical detector in an in vitro blood glucose self-monitoring system.

118.(Withdrawn)(Currently amended) An apparatus for a blood glucose self-monitoring system, the apparatus comprising:

a ball-point-pen shaped housing comprising an exterior surface and an opening at a bottom end;

a photometrical detector contained within an upper portion of said housing;

a display mounted on said surface for displaying measurement results;

an optical probe connected to said photometrical detector where in a first position said optical probe is contained within said housing to protect said optical probe from damage and in a second position a portion of said optical probe extends through said opening;

a button on a top of said housing for alternately moving said optical probe between said first and second positions when said button is depressed;

a clip attached to an upper portion of said housing for attachment to an article of clothing or other flat surface for securely transporting the apparatus;

a micro tube comprising a first open end, a second closed end and a first diameter along an entire length of said micro tube, said second closed end comprising an interior surface and an exterior surface wherein said first open end and said interior surface of said second closed end defines a cavity of said micro tube and said first open end and said exterior surface of said second closed end defines said entire length of said micro tube, said first open end receiving said optical

probe when said optical probe is in said second position where said optical probe passes through said cavity to said interior surface of said second end;

a reagent pad comprising a flat membrane material impregnated with a dried reagent solution that comprises oxidase/peroxidase enzymes and optical properties that change with a quantity of glucose, said flat membrane material formed in a circular shape with a second diameter matching said first diameter for substantially covering said second end while minimizing an area of said reagent pad, said reagent pad further comprising a first flat surface for contacting a sample of blood and a second flat surface, wherein said minimized area of said reagent pad minimizes a volume of the sample of blood required for testing; and

means for bonding said second flat surface to said exterior surface of said second end where light from said optical probe impinges on said second flat surface and a reflected light, from said second flat surface, indicating changes in said optical properties is effectively returned through said optical probe to said photometrical detector where the quantity of the glucose in the minimized volume of the sample of blood can be measured in vitro.

119.(Withdrawn)(Original) The device as recited in claim 118, wherein said optical probe is removably inserted into said first open end and said micro tube is disposable.

120.(Withdrawn)(Original) The device as recited in claim 118, wherein said change in optical properties is a color change.

121.(Withdrawn)(Original) The device as recited in claim 118, wherein said flat membrane material further comprises a uniformly porous hydrophilic membrane.

R E M A R K S

Reconsideration of the application is respectfully requested based on the following remarks.

In the Office Action, the Examiner rejected claims 105-109, 111-115 and 117. Claims 110 and 116 were objected to as being dependent on rejected base claims. Claims 118-121 were withdrawn from consideration. Claims 105, 111, 112, 117 and 118 have been amended herein. Claims 110 and 116 have been canceled without prejudice or disclaimer. Claims 105-109, 111-115 and 117-121 are pending.

ALLOWABLE SUBJECT MATTER

The Examiner's indication of allowable subject matter in the application is gratefully acknowledged. The Examiner stated, "Claims 111 and 116 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art Peterson et al. teach a reagents for the measurements of oxygen and does not teach the claimed oxidase/peroxidase enzymes." Given the Examiner's reasons for indication of allowable subject matter, Applicant believes that there was an error of a typographical nature and that claims 110 and 116 contain the allowable subject matter. Claim 111 does not include the limitation of "oxidase/peroxidase enzymes". Claims 110 and 116 do include this limitation.

Applicant has herein amended independent claim 105 to include the allowable subject matter of claim 110. Applicant has also herein amended independent claim 112 to include allowable subject matter of claim 116. Thus, it is respectfully submitted that claim 105 and claim 112 are patentable over the cited art for reasons stated by the Examiner. As such, Applicant believes that independent claim 105, dependent claims 106-109 and 111, independent claim 112 and dependent claims 113-115 and 117 are patentable over the cited art and in condition for allowance. Applicant respectfully requests that the Examiner to allow pending claims 105-109, 111-115 and 117.

CLAIM REJECTIONS UNDER 35 USC §112

In the Office Action, the Examiner rejected claims 111 and 117 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated, “It is not clear what structure element of the apparatus will permit glucose self monitoring. Clarification could be achieved if Application were to claim a reagent for detecting glucose.” Applicant has herein amended claims 111 and 117 to now recite in relevant part “...wherein **said reagent solution reacts to blood glucose and the quantity of the blood glucose in the minimized size of the sample volume is measured by the photometrical detector in an in vitro blood glucose self-monitoring system.**”

Applicant believes that the above issues have been fully addressed and respectfully request the Examiner to withdraw the 35 U.S.C. 112, second paragraph rejections of claims 111 and 117.

REJECTION OF CLAIMS 105-109 and 112-115 UNDER 35 USC §103(a)

In the Office Action, the Examiner rejected claims 105-109 and 112-115 under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (USP 4,476,870). Applicant respectfully disagrees.

Regarding independent claims 105 and 112, the Examiner stated, “Peterson teaches a fiber optic probe for the measurement of physiological properties. The probe comprises two optical fibers(12,14) where each fiber has a first and second end where the first end receives light and the second end is in contact with a suitable support and indicator dye. Column 6 lines 32-38 teach the support could be the hydrophilic polymer "Amberlite XAD4" as has been read on the claimed "reagent pad." Figure 4 illustrates the polymer support has a greater diameter than the two optical fibers(12,14).” Applicant respectfully disagrees that Peterson teaches Applicant’s reagent pad. Peterson teaches the dye 15, on an adsorbent support 16, is contained inside a section of tubing 10 of porous polyethylene, providing rapid equilibration with the surrounding oxygen and isolating the

dye packing 16 from contamination (column 5, lines 9-13). Peterson further teaches a liquid-water-impermeable container of high oxygen permeability is required for the permeable envelope 10 (column 6, lines 39-41). Peterson's dye and absorbent support is contained within a tube. This tube only allows the oxygen to contact the dye and absorbent support. Peterson teaches that the dye packing is to be isolated by the tube to prevent contamination. In contrast, Applicant claims **said reagent pad further comprising a first flat surface for contacting the sample volume**. The sample volume contains the analyte to be measured. One of ordinary skill in the art would not be motivated by the teaching of Peterson to produce Applicant's reagent pad and have reasonable likelihood of success. Applicant further notes that when determining whether a claim is obvious, an Examiner must make a comparison of the claimed invention, including all its limitation, with the teaching of the prior art (see Ex parte Wada and Murphy, BPAI Appeal No. 2007-3733 (January 14, 2008)).

Furthermore, Applicant has herein amended claims 105 and 112 with the limitation of oxidase/peroxidase enzymes that the Examiner indicated as allowable. At least, for all the reasons given, Applicant believes that all of the art of record, alone or in combination does not provide sufficient teaching, suggestion or motivation that would motivate one of ordinary skill in the art to try to combine elements to achieve Applicant's novel invention. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejections of claims 105-109 and 112-115 and allow these claims.

In view of the foregoing discussion all objections and rejections are believed overcome, and Applicant respectfully requests that all rejections be withdrawn and pending claims 105-109, 111-115 and 117 be allowed.

WITHDRAWN CLAIMS 118-121

Upon allowance of pending claims 105-109, 111-115 and 117, Applicant respectfully requests the Examiner to consider rejoinder of withdrawn claims 118-121. Independent claim 118, of group II, is a combination claim where the combination as claimed requires the details of subcombination claim 112, of group I, as separately

claimed. As such there is no evidence that combination claim 118 is patentable without the details of subcombination claim 112. The inventions are not distinct and a requirement for restriction cannot be made or maintained, even if the subcombination has separate utility. See MPEP § 806.05(c).

OTHER CITED REFERENCES

The Examiner also cited other references on PTO Form-892, but did not use these references to reject the claims. As implied by the fact that these references were not used to reject the claims, these additional references do not teach or suggest the features of Applicant's claimed invention. Thus, it is submitted that all claims are patentably distinct from these additional references.

CONCLUSION

It is submitted that cited references, alone or in any combination, do not teach, suggest or motivate one of ordinary skill in the art to produce Applicant's novel test tip device. Therefore, it is submitted that claims 105-109, 111-115 and 117 are patentably distinct from the cited references. Reconsideration of the application and a Notice of Allowance are earnestly solicited.

If there are any issues remaining which the Examiner believes could be resolved through either a Supplemental Response, an Examiner's Amendment, or otherwise if the Examiner believes that further discussion would expedite the prosecution of this application, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Applicant believes that a one-month extension fees are due in connection with this filing. Applicant hereby petition for an extension of time which may be required to maintain the pendency of this case, and for any required fee for such extension or any further fee required in connection with the filing of this Amendment, the Commissioner is hereby authorized to charge any required fees not included with this paper directly to the credit card indicated in the attached Credit Card Payment form PTO-2038. In any

case, it is requested that the Commissioner notify Applicant of any payment due that is not otherwise paid with this letter.

Respectfully submitted,
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